

Applicants: Spiridigliozi, et al.
Application No.: 10/643,315
Filing Date: August 19, 2003
Page 10

Remarks/Arguments:

Introduction

Claims 1-47 are pending. Claims 16, 18, 34, 36 and 38-47 are withdrawn from consideration as being directed to a non-elected invention. Claims 1-15, 17, 19-33, 35 and 37 are rejected.

Section 103 Rejections

The Examiner has rejected Claims 1-15, 17, 19-33 and 37 under 35 U.S.C. 103 (a) as being unpatentable over U.S. Patent No. 4,850,999 to Planck (hereinafter “Planck”) in view of U. S. Patent 6,264,684 to Banas (hereinafter “Banas”) and further in view of U.S. Patent No. 5,628,788 to Pinchuk, (hereinafter “Pinchuk”).

Applicants respectfully traverse the rejections for reasons expressed below.

Planck has been cited for its alleged teaching regarding “composite multilayer implantable structure.” Action, pg 4. The Examiner states that 12' and 12” in Figure 1 are distinct layers. This interpretation is incorrect. They are a single layer in which the stent (braided hose) is embedded. This will be more fully addressed below.

Banas has been cited for its alleged teachings of “applying the graft providing crimps”. Action, p. 3.

Banas and Planck May Not be Properly Combined

Planck’s braided textile or braided metallic layer is directed only to braided hoses which are “flexible, elastic threads fashioned in the form of a hollow meshwork . . .” Col 1, lines 45-47. The braided hose is intended to impart “increased resistance against buckling and compression,” and is commonly referred to in current terms as a stent. Col. 1, line 49. The braided hose is embedded in

Applicants: Spiridigliozi, et al.

Application No.: 10/643,315

Filing Date: August 19, 2003

Page 11

the tubular layer. The reference to the hose subdividing the tubular layer is merely describing the position of the hose within a single polymer layer. Thus, Planck does not teach or suggest two distinct ePTFE layers, which are joined together.

Applicants therefore contend that a *prima facie* case of obviousness has not been established. Among the criteria necessary for establishing a *prima facie* case of obviousness, there must be a reasonable expectation of success of the combined references. If there is no such reasonable expectation of success, the prior art may not be combined. *See, e.g.* MPEP 2143.02. Applicants respectfully contend that the hypothetical combination of Banas and Planck does not provide a reasonable expectation of success.

The Examiner uses Banas to provide a bonding agent, and Planck to provide a textile layer. However, Banas in view of Planck can not reasonably be expected to successfully perform because there is no teaching or suggestion in Banas that the disclosed bonding agent is suitable for bonding ePTFE (the “first inner tubular layer,” as recited in applicants’ claim 1) to a textile (the “second tubular layer” as recited in applicants’ claim 1). Banas is directed to a wire member made of “either a shape memory alloy, preferably a nickel-titanium alloy known as NITINOL, spring stainless steel or other elastic metal or plastic alloys, or composite material, such as carbon fiber.” (col. 3, lines 13-16). The wire member is bonded to a tubular substrate made of a “biocompatible polymeric material, such as expanded polytetrafluoroethylene (‘ePTFE’), polyethylene terephthalate (‘PET’)... or polyurethane.” (col. 6., lines 4-8). The bonding agent of Banas is used to attach the wire member to the ePTFE tubular substrate. However, there is no disclosure in Banas that the wire member may be made of a textile. The wire member of Banas therefore cannot be expected to have the same properties as the textile layer of Planck. Unless there is a teaching or suggestion to the contrary in the reference, a bonding agent suitable for use with a “wire member” cannot be expected to have the same properties as a bonding agent suitable for use with a textile. Note that “the teaching or suggestion to make the claimed combination and the reasonable expectation of success *must be found in the prior art*, and not based on applicants’ disclosure.” MPEP 2142, citing *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991) (emphasis added).

Applicants: Spiridigliootti, et al.
Application No.: 10/643,315
Filing Date: August 19, 2003
Page 12

Applicants are unable to find any suggestion in Banas that the bonding agent disclosed therein is suitable for use with textiles, as there is no mention whatsoever of textiles in Banas. Accordingly, there is no reason to assume that a bonding agent suitable for bonding a wire member to ePTFE is suitable for bonding a textile layer to ePTFE.

Because there appears to be no reasonable expectation that the bonding agent of Banas would successfully bond the textile layer to the outer tubular ePTFE layer of Planck, the two references can not be combined. Applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Banas and Planck Do Not Teach Each and Every Element of the Invention as Claimed

“To establish a *prima facie* case of obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” MPEP 2143.03, citing *In re Royka*, 490 F.2d 981 (CCPA 1974). As previously stated above, Planck does not disclose, teach or suggest two discrete ePTFE layers or two other discrete polymer layers in which the hose (stent) is embedded. In applicants’ claims, the first inner tubular layer and the second outer tubular layer are each recited as being distinct elements and therefore being made from separate layers. Thus, explicit in the claims is the requirement that two layers be combined. This is in contrast to the allegedly corresponding layers 12’ and 12” of Planck. Layers 12’ and 12” of Planck are actually one layer, layer 12, with a braided hose embedded therein. As stated in Planck, the “braided hose 11 is coaxial to the layer 12 in which it is embedded and subdivides the layer *practically* into two sublayers 12’ and 12”.” Clearly, by use of the word “practically,” Planck contemplates something other than complete subdivision of layer 12. Construing 12’ and 12” to be two distinct and discrete layers would be ignoring Planck’s plain acknowledgement to the contrary.

Pinchuck Does Not Cure The Deficiencies of Banas and Planck

The only new prior art which the Examiner applies in the Office Action is Pinchuck ‘788. As stated above, the newly added Pinchuk ‘788 adds nothing more than the previously cited, and

Applicants: Spiridigliozi, et al.

Application No.: 10/643,315

Filing Date: August 19, 2003

Page 13

apparently withdrawn, Pinchuk had to offer. The Examiner alleges on page 5 of the Office Action that Planck as modified by Banas discloses the implantable device as claimed. However, the Examiner acknowledges that Planck as modified by Banas fails to disclose that the bonding agent comprises a polycarbonate urethane and is applied in a solution of dimethylacetamide. The Examiner then alleges that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the implantable stent graft disclosed by Planck and modified by Banas by incorporating a polycarbonate urethane bonding solution of dimethylacetamide as taught by Pinchuck in order to speed up the polymerization of the polyurethane."

In response, applicants respectfully traverse the Examiner's rejection.

Pinchuck '788 is cited for its disclosure of a polycarbonate urethane bonding agent. Applicants contend, however, that Pinchuck '788 fails to remedy the above-described deficiencies of Banas and Planck. Applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Summary

In summary, the Examiner has taken a reference (Planck) which lacks two ePTFE layers, a bonding agent, a solvent for the bonding agent, and spaced crimps. He then cites Banas to fill in the gaps missing in Planck. However, Banas is directed to bonding ePTFE to a metallic stent and although it discloses a bonding agent, it is not the same agent as claimed. Thus, Banas does not teach bonding two ePTFE layers together via the adhesive. Furthermore, Banas is directed only to two ePTFE layers being joined and is silent about textiles. Thus, grafts made by Banas are very different than those made by Planck. Whereas Banas' adhesive joins a metal stent to ePTFE, the Examiner is attempting to combine the teachings of Banas and Planck to arrive at applicants' use of the recited adhesives to join the textile layer to the ePTFE layer. This is clearly hindsight in construction. Moreover, even if the references were properly combinable, such a combination would clearly not produce the claimed invention. At best, the skilled artisan might be guided to use adhesive to adhere Planck's hose (stent) to this ePTFE polymer layer 12. Further, the fact that

Applicants: Spiridigliozi, et al.
Application No.: 10/643,315
Filing Date: August 19, 2003
Page 14

Pinchuk '788 discloses the use of polyurethane and dimethylacetamide solvent for grafts adds nothing to remedy the basic insufficient in Planck and Banas, alone or in combination.

Double Patenting Rejection

Upon indication of allowable subject matter, Applicant will file a terminal disclaimer to obviate the judicially created doctrine of obviousness-type double patenting over the claims of co-pending Application No. 10/166,842.

Should the Examiner have any questions or comments concerning this matter, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number set forth below.

Respectfully submitted,



Stephen Cannavale
Reg. No. 44,585
Attorney for Applicant

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700